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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,279	04/19/2007	Kerstin Ehlert	Le A 36 810	9770

35969 7590 06/05/2008

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EXAMINER
FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
1652	

MAIL DATE	DELIVERY MODE
06/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,279	EHLERT ET AL.	
	Examiner	Art Unit	
	CHRISTIAN L. FRONDA	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) *5-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/3/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group I, claims 1-4, in the reply filed on 05/06/2008 is acknowledged. The traversal is on the ground(s) that the restriction requirement is not warranted because the PCT held that all claims could be examined together. This is not found persuasive for reasons of record as further explained.

As previously stated, a same or corresponding technical feature shared among Inventions 1 and 2 is any DNA material comprising the xlyA promoter, ribosome binding site from a Gram-positive bacterium, and a reporter gene. Sizemore et al. (J Bacteriol. 1992 May;174(9):3042-8; reference of record) teach such DNA material, specifically, a DNA construct comprising the xylAB regulatory region fused to a lipase gene which is the reporter gene. Furthermore, Bhavsar et al. (Appl Environ Microbiol. 2001 Jan;67(1):403-10; PTO 892) teach the plasmid pSWEET comprising the xylA promoter, ribosome binding site from *B. subtilis*, a reporter gene encoding a thermostable β-galactosidase reporter which is operably linked to the promoter, a selection marker for chloramphenicol, and an origin of replication.

Thus, the same or corresponding technical feature is not special since it was known in the prior art and therefore cannot make a contribution over the prior art. Since the inventions lack the same or corresponding special technical feature, then the inventions listed as Invention 1 and Invention 2 are not so linked as to form a single general inventive concept under PCT Rule 13.1. The requirement is still deemed proper and is therefore made FINAL. Claims 5-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

2. Claims 1-4 are under consideration in this Office Action.

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 U.S.C. § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1-4 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

The claims as written do not sufficiently distinguish over nucleic acids and/or DNA as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "an isolated DNA" or "a purified DNA". See MPEP 2105.

Claim Rejections - 35 U.S.C. § 112, First Paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated DNA comprising the sequence of SEQ ID NO: 5 or SEQ ID NO: 6; **does not** reasonably provide enablement for any DNA material comprising any sequence that is at least 90% identical to the sequence of SEQ ID NO: 5 or SEQ ID NO: 6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

According to MPEP 2164.01(a), factors considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

MPEP§ 2164.04 states that while the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP § 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written enablement rejection. The language should focus on those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. Accordingly, the factors most relevant to the instant rejection are addressed in detail below.

The nature and breadth of the claim encompasses any DNA material comprising any sequence that is at least 90% identical to the sequence of SEQ ID NO: 5 or SEQ ID NO: 6.

The specification discloses an isolated polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 5 and an isolated polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 6. However, the specification does not provide guidance, prediction, and working examples showing a correlation between any structure, nucleotide composition, and nucleotide sequence of the nucleic acid molecules as claimed and its biological function. There

is no art-recognized correlation between any structure, nucleotide composition, and nucleotide sequence of the nucleic acid molecules as claimed and its biological function. The specification does not provide guidance, prediction, and working examples regarding the specific nucleotides in SEQ ID NO: 5 and SEQ ID NO: 6 to change without affecting the biological activity of the DNA material as claimed.

Thus, one must perform an enormous amount of trial and error experimentation to search and screen for the claimed nucleic acids from any biological source or chemically synthesize the nucleic acids and determine if their biological function. General teaching regarding screening and searching for the claimed invention using the aggregation assays stated in the specification is not guidance for making the claimed invention.

Therefore, in view of the overly broad scope of the claims, the specification's lack of specific guidance and prediction, the specification's lack of additional working examples, and the amount of experimentation required; it would require undue experimentation for a skilled artisan to make and use to make and use the entire scope of the claimed invention recited in claim 4.

Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970). Without sufficient guidance, the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988).

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Bhavsar et al. (Appl Environ Microbiol. 2001 Jan;67(1):403-10; PTO 892).

Bhavsar et al. teach the plasmid pSWEET comprising the xylA promoter, ribosome binding site from *B. subtilis*, a reporter gene encoding a thermostable β-galactosidase reporter which is operably linked to the promoter, a selection marker for chloramphenicol, and an origin of replication. See entire publication especially pages 403-405 and Figs. 1-6. Thus, the reference teachings anticipate the claims.

Claim Rejections - 35 U.S.C. § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

According to MPEP 2143:

> "Exemplary rationales that may support a conclusion of obviousness include:
>
> (A) Combining prior art elements according to known methods to yield predictable results;
>
> (B) Simple substitution of one known element for another to obtain predictable results;
>
> (C) Use of known technique to improve similar devices (methods, or products) in the same way;
>
> (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
>
> (E) " Obvious to try " – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
>
> (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
>
> (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

> Note that the list of rationales provided is not intended to be an all-inclusive list. Other rationales to support a conclusion of obviousness may be relied upon by Office personnel."

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bhavsar et al. (Appl Environ Microbiol. 2001 Jan;67(1):403-10; PTO 892) in view of Kain et al. (Curr Protoc Mol Biol. 2001 May;Chapter 9: Unit9.6; PTO 892).

The teachings of Bhavsar et al. have been stated above. The teachings of the reference differ from the claims in that the plasmid pSWEET does not contain the luciferase reporter gene

Kain et al. teach the luciferase reporter gene, where luciferase is a widely used reporter enzyme which is much faster and more sensitive than the chloramphenicol acetyltransferase (CAT) assay and does not use radioactivity. See entire publication.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the plasmid pSWEET of Bhavsar et al. such that the thermostable β-galactosidase reporter gene is replaced with the luciferase reporter gene taught by Kain et al. One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to have a reporter system that can predictably be used in measuring gene expression, where luciferase is a widely used reporter enzyme which is much faster and more sensitive than the CAT assay and does not use radioactivity. One of ordinary skill in the art at

the time the invention was made would have a reasonable expectation of success because the art of molecular biology and recombinant DNA manipulation are well known and developed.

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Thursday and alternate Fridays between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on (571)272-0934. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christian L. Fronda/
Patent Examiner
Art Unit 1652